

ELECTRIFYING THE FUTURE

Development of Colorado's Water Quality Standard for Molybdenum

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Overview

- Introductions
- Background on molybdenum standard and temporary modification
- Update on new developmental/reproductive toxicity study in rats given a marginal copper diet
- Water supply standard based on WQCC Policy 96-2
- Treatment plant status
- Next steps

Background on Molybdenum Standard and Temporary Modification

- 2010: WQCC adopts 210 ug/L in Reg. #31 based on Fungwe
- 2014: WQCC adopts standard in Reg. #33 along with temp mod for portion of Tenmile Creek (Blue River Segment 14)
- 2017: Molybdenum standards hearing (continued and then later postponed pending ATSDR Mo tox profile)
- 2018-2022: WQCC extends temp mod to accommodate delay in ATSDR profile and changes to WQCC hearing schedule



Progress on Temporary Modification

- Climax continues to maintain current condition
 - Achieving current conditions by temporarily modifying mine plan
 - Begin construction of molybdenum removal water treatment plant (MRWTP) to maintain current conditions and have mine plan flexibility
- Climax continues to monitor water quality
 - Worked with local stakeholders to identify locations to sample Mo concentrations
 - Data made available to the public on ClimaxMoinCO.com



Progress on Temporary Modification

- Significant advances in science
 - Publication of 3 state-of-the art molybdenum studies
 - Independent review, including by ATSDR
 - ATSDR profile published in May 2020
 - New CRL study completed 2022
- More detail provided in annual updates

Update on New Developmental/ Reproductive Toxicity Study in Rats Given a Marginal Copper Diet

Dr. Jay Murray

Introduction

- Climax sponsored a recent study to determine whether the Fungwe study results can be replicated
- Climax notified the stakeholders in advance of conducting this study
- Conducted at Charles River Laboratories (CRL, Horsham, PA)
 - Study will be published in a peer-reviewed journal
- These are results based on the 750-page draft report from CRL
- The results prove that the Fungwe study is not reproducible and not reliable

Background

- In 1990, Fungwe reported developmental and reproductive toxicity in rats given molybdenum (Mo) in the drinking water and maintained on a marginal copper (Cu) semi-synthetic diet
- The Fungwe study has many serious limitations, which has called into question its reliability
- The toxic effects reported by Fungwe were not observed in recent peer-reviewed and published guideline toxicity studies of Mo
- ATSDR excluded the Fungwe study as the critical study for its risk assessment because of its limitations, but ATSDR applied a modifying factor (MF) of 3 based on the Fungwe study

Basis for ATSDR modifying factor (MF) of 3

“3 MF for concern that reproductive and/or developmental effects may be a more sensitive endpoint than kidney effects in populations with marginal copper intakes. The copper content of the Murray et al. (2014b, 2019) reproductive/developmental studies used a commercial diet with a fairly high copper content. In contrast, the Fungwe et al. (1990) study, which reported reproductive effects, utilized a diet that was slightly higher than the dietary requirement. The differences in the copper contents of the diet may explain differences between the study results.”

-- ATSDR Toxicological Profile for Molybdenum (2020), p. A-20 to A-21.

Why was this study conducted?

- “Additional studies are needed to provide insight into the apparent conflicting results.” -- ATSDR (2020)
- In 2017 hearing, WQCD suggested a study to see if the results of Fungwe could be replicated
- In response, the current study was designed to replicate the design of the Fungwe study
- The potential developmental and reproductive toxicity of Mo was assessed in female Sprague-Dawley rats
 - administered Mo in the drinking water
 - maintained on a semi-purified diet with a marginal copper level of 6.2 ppm to match the Fungwe study (reported as 6.3 ppm)

Overview of Findings

- The study did not confirm any of Fungwe's adverse findings
- The NOAEL for developmental toxicity in the CRL study is 40 mg Mo/kg/day, the highest dose tested
- This is the same NOAEL for developmental toxicity observed in the first IMOA developmental toxicity study
- In other words, the CRL study shows that Mo dosing in combination with a marginal copper diet does not cause developmental toxicity at doses up to 40 mg Mo/kg/day

Experimental Design

- 0, 20 and 40 mg Mo/kg/day in the drinking water
- Marginal copper semi-synthetic diet (6.2 ppm Cu) given to all groups
- 8 weeks prior to mating, 2-week mating period, and 3 weeks of gestation
- CRL study design is virtually the same as the Fungwe study

No Test Material-Related Adverse Effect on Dams or Fetuses

- mortality
- clinical observations
- body weight
- body weight gain
- food consumption
- estrous cycling
- reproductive performance
- maternal macroscopic pathology
- # of fetuses
- # of live fetuses
- resorptions
- sex ratio
- fetal body wt.
- external malformations
- external variations

Draft Report Conclusion by CRL Toxicologists

“Therefore, based on these results, the systemic toxicity, maternal and developmental no-observed-adverse-effect levels (NOAELs) were considered to be 40 mg Mo/kg bw/day.”

Comparison of Results: Fungwe vs. CRL Study

Presumed Fungwe doses: 0, **0.76**, 1.5, 7.6, 15 mg Mo/kg bw/day (ATSDR, 2020)

CRL study actual doses: 0, 20, **40** mg Mo/kg bw/day

- *Fungwe: Prolonged estrous cycle at doses of 1.5 mg/kg/day and greater (extended by 6-12 hrs in most animals)*
- CRL: No significant effect on estrous cycle at 20 or 40 mg/kg/day (4.41, 4.38, 4.47 day average length of cycle at 0, 20, and 40 mg Mo/kg bw/day)
- *Fungwe: 1.5 mg/kg/day and greater “tended to have fewer pups”*
- CRL: No significant effect on the average number of fetuses or average number of live fetuses at 20 or 40 mg/kg/day
- *Fungwe: 1.5 and greater “fetuses were significantly smaller and weighed less.” (7%, 9%, 32%, and 27% decrease at 0.76, 1.5, 7.6, and 15 mg/kg/day)*
- CRL: No statistically significant effect on fetal body weight at 20 or 40 mg/kg/day (6% and 5% decrease at 20 and 40 mg/kg/day, respectively)

Why is the Fungwe study not reproducible and not reliable?

- Subject to speculation
- ATSDR noted it may have underestimated the dose levels used by Fungwe based on comparison of liver Mo concentrations; Fungwe did not analyze the levels of Mo in drinking water
- Fungwe did not analyze his diet for copper, and the liver copper (Cu) levels were 8-times greater than rats on an adequate Cu diet, suggesting his diet was not a marginal Cu diet
- Many limitations and errors identified previously
- The conflicting results have nothing to do with a marginal Cu diet

Conclusions

- Strongest evidence to date that the Fungwe study is unreliable and irreproducible
- The NOAEL for developmental toxicity in rats is 40 mg Mo/kg/day whether the copper level in the diet is adequate or marginal
- ATSDR's MF of 3 is not scientifically justified
- The Fungwe study (basis for Colorado's Mo WQS) should not be relied upon by any regulatory agency
- The IMOA and the CRL studies represent the best scientific information available concerning the toxicity of Mo

Policy 96-2 and RfD

Equation 1-1: DWS/MCLG, $\mu\text{g/l} = \frac{\text{RfD} \times 70 \times 1000 \mu\text{g/mg} \times \text{RSC}}{2 \times \text{UF}}$

where:

RfD ²	=	verified reference dose for non-carcinogens, mg/kg-day
70	=	weight of an average adult, kg
2	=	daily drinking water consumption, liters/day
RSC ³	=	relative source contribution (0.2 is default value)
UF	=	Uncertainty Factor (1.0 for most chemicals, 10 for certain Group C chemicals)

Calculation of the RfD

- RfD is calculated by applying UF and MF (if appropriate) to the NOAEL
 - ATSDR added total UF of 100 and MF of 3
 - MF of 3 based on Fungwe without opportunity for public comment; not included in the draft ATSDR profile
- For purposes of a prompt hearing and to build consensus Climax will accept ATSDR's total UF of 100 (10x10) even though CO's current standard, which is based on debunked science, uses a total UF of 30.
- However, MF of 3 not supported by best scientific information, and it should be removed

Source	NOAEL, mg/kg/day	UF Inter-species	UF Intra-species	Modifying Factor	Calculated RfD
ATSDR MRL	17	10	10	3	0.06
Climax	17	10	10	1	0.17

Recommended Input Factors

- RfD = 0.17 mg/kg/day
 - Applies ATSDR's chosen NOAEL, and ATSDR's UF of 100
 - Does not include MF based on updated science
- RSC = 0.8
 - Applies EPA's recommended RSC from 2017 hearing, as further confirmed by the Produce Study
- Body weight = 80 kg; Drinking water intake = 2.4 L
 - Based on updated science, and approved by WQCC and WQCD

Policy 96-2 Equation: Two Scenarios

$$1: \quad \text{DWS/MCLG, } \mu\text{g/L} = \frac{0.17 \times 80 \times 1000 \mu\text{g/L} \times 0.8}{2.4 \times 1} = 4350 \mu\text{g/L (chronic)}$$

Where:

- 0.17 = Calculated RfD (without MF), in mg/kg/day
- 80 = weight of an average adult in kg
- 2.4 = daily drinking water consumption in liters/day
- 0.8 = RSC

$$2: \quad \text{DWS/MCLG, } \mu\text{g/L} = \frac{0.06 \times 80 \times 1000 \mu\text{g/L} \times 0.8}{2.4 \times 1} = 1600 \mu\text{g/L (chronic)}$$

Where:

- 0.06 = Calculated RfD (with MF=3), in mg/kg/day
- 80 = weight of an average adult in kg
- 2.4 = daily drinking water consumption in liters/day
- 0.8 = RSC

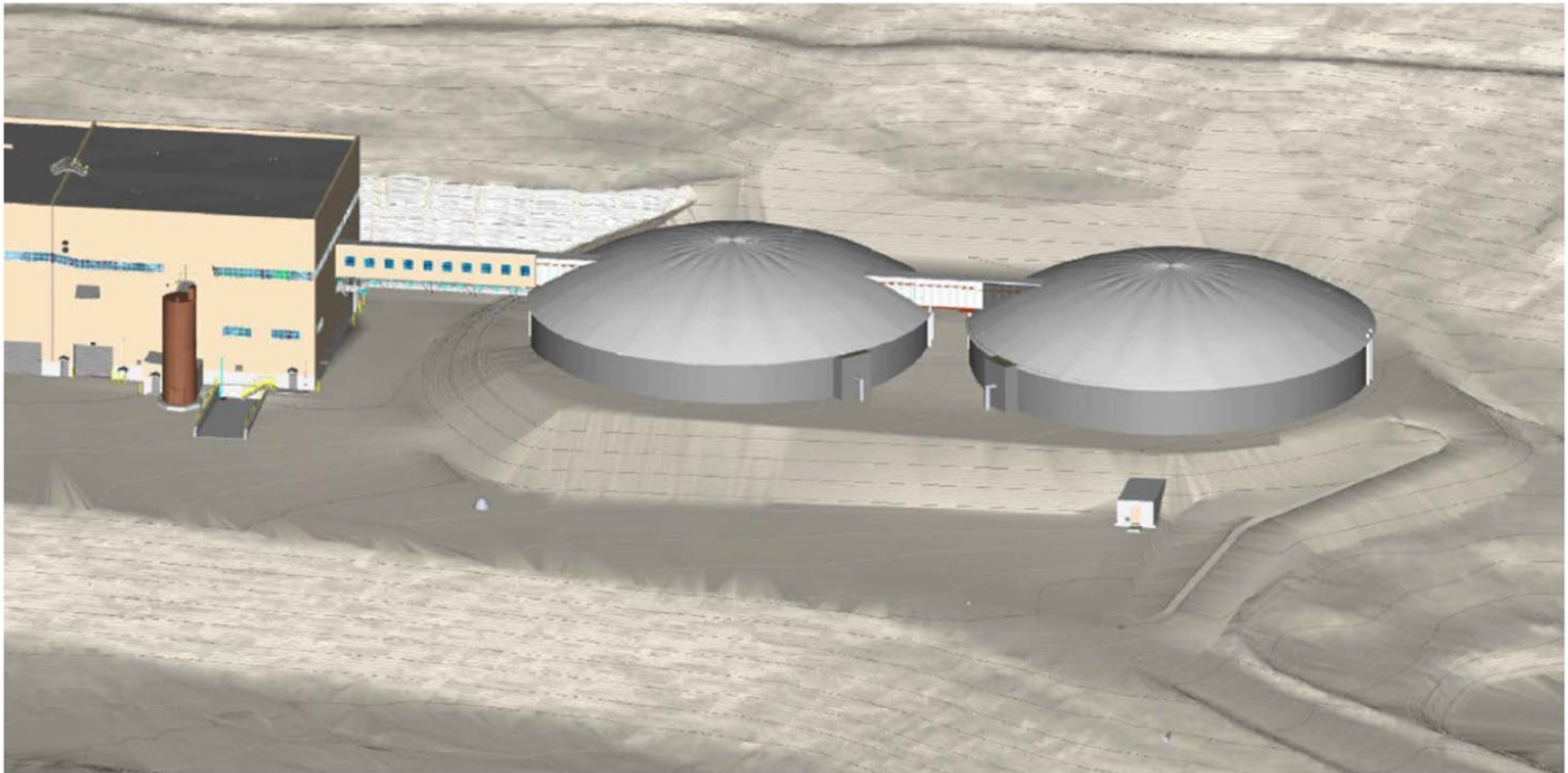
Recap of Treatment Alternatives

	Alternative 1	Alternative 1A	Alternative 2	Alternative 3
Description	Full Flow MRWTP with sand filters	Full Flow MRWTP without sand filters	MRWTP 75% of full flow	MRWTP 50% of full flow
CAPEX estimate <i>(Q2 2022 Dollars)</i>	\$155,000,000- \$163,000,000	\$112,000,000- \$120,000,000	\$125,000,000- \$134,000,000	\$95,000,000- \$103,000,000
OPEX estimate <i>(Q3 2021 Dollars)</i>	\$3,688,000	\$3,318,000	\$3,242,000	\$2,724,000
Flow at capacity, gpm	14,000	14,000	10,500	7,000
Molybdenum effluent criteria with low exceedance risk	210 ug/l	1,000 ug/l	4,330 ug/l	7,660 ug/l
Duration to implement <i>(2020 Estimate)</i>	3 yrs	2.5 yrs	3 yrs	3 yrs
Treatment Plant Still Needed after closure	Yes	Under Investigation	No	No

Update on Treatment Plant

- Climax pursuing Alternative 1A (full flow MRWTP without sand filters)
 - DRMS approved technical revision for the construction on May 31, 2022
 - Tenmile Planning Commission in Summit County approved Climax's request for site plan review on July 14, 2022
 - Grading and Excavation permit issued July 13
 - Construction stormwater permit issued by WQCD July 21
 - Construction kicked off July 18, with groundbreaking July 27

Update on Treatment Plant



3D Model of MRWTP

Update on Treatment Plant



3D Rendering of the PDWTP with MRWTP

Next Steps

- Rulemaking scheduled for June 2023
 - Proposal due mid-January 2023
 - Climax's prehearing statement due early March 2023
 - Responsive prehearing statements due early April 2023
- Stakeholder discussions to try to arrive at consensus
 - More discussions to be scheduled depending on stakeholder interest and time
- Only two issues need to be resolved:
 - Should the RfD be calculated without the extra MF that was based on a discredited and unreliable study?
 - Should an RSC of 0.8 be applied given low dietary intake of molybdenum?